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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/727,737 | 12/03/2003 | Paula M. Jardieu | P1064R1CI | 6064 |
| 9157 | 7590 | 10/28/2005 | EXAMINER | |
| GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080 | | | TUNGATURTHI, PARITHOSH K | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1643 | | |

DATE MAILED: 10/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/727,737 | JARDIEU ET AL. |
| | Examiner | Art Unit |
| | Parithosh K. Tungaturthi | 1643 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 1-4 and 6-13 link(s) inventions I-V as set forth above. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1-4 and 6-13. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

- I. Claim 5 in part drawn to an antibody mutant wherein the nonhuman primate is rhesus, classified in class 530 and subclass 387.1+ for example.
- II. Claim 5 in part drawn to an antibody mutant wherein the nonhuman primate is cynomolgus, classified in class 530 and subclass 387.1+ for example.
- III. Claim 5 in part drawn to an antibody mutant wherein the nonhuman primate is baboon, classified in class 530 and subclass 387.1+ for example.

- IV. Claim 5 in part drawn to an antibody mutant wherein the nonhuman primate is chimpanzee, classified in class 530 and subclass 387.1+ for example.
- V. Claim 5 in part drawn to an antibody mutant wherein the nonhuman primate is macaque, classified in class 530 and subclass 387.1+ for example.
- VI. Claims 14-16, drawn to a method of producing an antibody mutant comprising substitution an amino acid residues in a hypervariable regions of a species-dependent antibody, classified in class 435 subclass 71.1+ for example.
- VII. Claims 17-22, drawn to a method of making an antibody mutant, classified in class 435 subclass 71.1+ for example.
- VIII. Claims 23-28, drawn to an isolated nucleic acid encoding the antibody and a process of producing antibody mutant comprising culturing the host cells so the nucleic acid expressed, classified in class 536 subclass 23.1, and class 435 and subclass 71.1+.

2. The inventions are distinct, each from the other because of the following reasons: The antibodies of Groups I-V and the polynucleotide of Group VIII are patentably distinct for the following reasons: The antibodies of Groups I-V includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6

complementarily determining regions (CDRs). Polypeptides, such as the antibodies of Groups I-V which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group VIII will not encode any antibodies of Groups I-V, and the antibodies of Group I-V cannot be encoded by a polynucleotide of Group VIII. Therefore, the antibody and polynucleotide are patentably distinct. The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. In addition, the antibodies of Groups I-V are different among themselves because they consist of antibodies from different non-human primates selected from rhesus, cynomologus, baboon, chimpanzees and macaque; and because the amino acid coding sequence including the structure and the specificity towards an antigen can be different. Furthermore, searching the inventions of Group I-V and Group VIII would impose a serious search burden since a search of the polynucleotides of Group VIII would not be used to determine the patentability of any antibody of Groups I-V and vice-versa. Thus, the products of Groups I-V and VIII represent separate and distinct inventions.

The inventions of Groups VI and VII are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. In the instant case, Group VI recites a method of producing an antibody mutant comprising substitution an amino acid residues

in a hypervariable regions of a species-dependent antibody and Group VII recites a process of producing antibody mutant comprising culturing the host cells so the nucleic acid expressed. Thus, each group differs in method objectives, method steps and parameters and in the reagents used. Further, each group is unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has different mode of operation. Each invention further performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for detection differ significantly for each of the materials. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions VI and VII are separate and distinct in having different method steps and different endpoints and are patentably distinct.

Inventions I-V and Inventions VI-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies composition of groups I-V can be used in a materially different method such as immunoassays in addition to the materially different methods of groups VI and VII.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

matter and different searches in the patent literature and different classification, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order

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to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Parithosh K. Tungaturthi, Ph.D.

April 29, 2005



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER